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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/086,206	02/28/2002	Juana Magdalena	408.014-CON	1829
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Charles A. Muserlian c/o Bierman, Muserlian and Lucas 600 Third Avenue New York, NY 10016				
EXAMINER				
JOHANNSEN, DIANA B				
ART UNIT		PAPER NUMBER		
1634				

DATE MAILED: 07/01/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

**Application No.**

10/086,206

**Applicant(s)**

MAGDALENA ET AL.

**Examiner**

Diana B. Johannsen

**Art Unit**

1634

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 07 May 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 28-55 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 28-33,35-46,54 and 55 is/are rejected.
- 7) ☒ Claim(s) 33-36,38,39,41 and 47-53 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 28 February 2002 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☒ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☒ Certified copies of the priority documents have been received in Application No. 09/242,588.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

## DETAILED ACTION

### *Priority*

1. It is noted that this application is a continuation of application no. 09/242,588, filed May 20, 1999, now abandoned, which is a 371 of PCT/FR97/01483, filed August 12, 1997. The first line of the specification should be amended to provide the current status of application no. 09/242,588 (i.e., to insert the phrase "now abandoned").

### *Oath/Declaration*

2. The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because:  
Non-initialed and/or non-dated alterations have been made to the oath or declaration (see pages 2-3 of the oath/declaration). See 37 CFR 1.52(c).

### *Claim Objections*

3. Claims 34 and 47-53 are objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim may refer to other claims in the alternative only. Specifically, claims 34, 47, 48, 49, 52 and claims dependent therefrom depend from multiple claims improperly. See MPEP § 608.01(n).

**Accordingly, the claims 34 and 47-53 have not been further treated on the merits.** The claims will be considered at such time as they are amended so as to constitute proper dependent claims.

4. Claims 33, 35-36, 41, and 46 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a

previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Specifically, it is noted that claim 33 appears to be substantially broader than claim 28, from which it depends.

5. Claims 38-39 and 55 are objected to because of the following informalities. In claims 38-39, "pairs" is misspelled "paris." In claim 55, "regX3" is misspelled "regXe" (see step (1)). Appropriate correction is required.

***Specification***

6. The abstract of the disclosure is objected to because it consists of a single, incomplete sentence. It is further noted that the term "complementary" is misspelled "complimentary" in the abstract. Correction is required. See MPEP § 608.01(b).

7. The specification is objected to because it does not contain, as a separate section, a brief description of the drawings. Amendment of the specification to include a separate section briefly describing the content of each of the drawings, as set forth in 37 CFR 1.74, is required.

This rejection may be overcome by, e.g., amending page 14 of the specification at line 1 such that it recites the heading "Brief Description of the Drawings".

***Claim Rejections - 35 USC § 112***

8. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

9. Claims 28-33, 35-46, and 54-55 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 28-33, 35-46, and 54-55 are indefinite over the recitation of the phrases "A fragment of a nucleic acid specific to mycobacteria of *M. tuberculosis* complex" in claims 28-30, "specific sequences of nucleic acids of *M. tuberculosis* complex" in claims 37 and 55, "a specific nucleotide sequence of mycobacteria of *M. tuberculosis* complex" in claims 42 and 54-55, and "specific nucleic acids of mycobacteria strains of *M. tuberculosis* complex" in claim 55. It is unclear as to what is meant by the term "specific", and as to how this term is intended to limit the claims. For example, what structural and/or functional properties would be required of a nucleic acid in order for it to be considered "specific to members of the *M. tuberculosis* complex"? The claims should be amended so as to provide a clear description of those molecules that are intended to be encompassed by the claims. With respect to claims 28-30, it is further unclear as to whether it is the "fragment" or the "nucleic acid" that is "specific to mycobacteria...."

Claims 28, 31-33, 35-36, 41, and 45-46 are indefinite over the recitation of the terms "their complementary sequences" in claim 28. The specification does not provide a clear and limiting definition of the term "complementary" and it is unclear as to what is intended to be encompassed by this language. Specifically, it is unclear as to whether this phrase refers only to nucleic acids that are fully complementary to a particular sequence, or whether the claims may encompass nucleic acids with some lesser degree of complementarity. As a result, the

metes and bounds of the claims are unclear. This rejection could be overcome by amending claim 28 to recite, e.g., "...selected from the group consisting of SEQ ID NO: 1, the complement of SEQ ID NO: 1, SEQ ID NO: 2, and the complement of SEQ ID NO: 2."

Claim 30 is indefinite over the recitation of the phrase "which fragment is different from BCG." It is unclear as to whether this recitation is intended to indicate a difference between the recited fragment and, e.g., a homologous fragment in BCG, to encompass another type of difference with respect to BCG, etc. Clarification is required.

Claims 33, 35-36, 41, and 46 are indefinite over the recitation of the term "high stringency conditions" in claim 33. While the specification does set forth some "preferred" hybridization conditions that would be considered by a skilled artisan to constitute "high stringency" conditions, the specification at page 6 states that "In the context of the present invention, it is considered that the conditions of "high stringency" in which two nucleotide sequences can hybridize are the conditions defined by Sambrook et al., 1989, namely temperature conditions of between ( $T_m$  minus 5°C) and ( $T_m$  minus 30°C)". Accordingly, the teachings of the specification suggest that the language "high stringency" may be intended to encompass a variety of conditions, including many types of conditions that would not be considered by a skilled artisan to be of high stringency. Thus, it is unclear to one of skill in the art as to how the recitation "high stringency conditions" actually limits the instant claims.

Claims 31-32 are indefinite over the recitation of the phrase "a nucleic acid sequence of claim 28" in claim 31. It is unclear as to whether this language is intended to refer back to the "fragment of a nucleic acid" to which claim 28 is directed, or to the "nucleotide sequence" recited in claim 28. Clarification is required.

Claims 33, 35-36, 41, and 46 are indefinite because it is unclear as to how and whether claim 33 is intended to further limit claim 28, from which it depends. Claim 33 is drawn to a "nucleotide probe or nucleotide primer that hybridizes under high stringency conditions with one of the sequences of claim 28, its corresponding RNA sequences or its corresponding gene". Accordingly, it appears that claim 33 may not be further limiting of claim 28, as would be required of a proper dependent claim. For example, the recitation a probe "that hybridizes under high stringency conditions with one of the sequences of claim 28" would encompass numerous molecules that would hybridize with the molecules of claim 28, whereas claim 28 is limited to molecules having particular sequences. Clarification is required.

Claims 33, 35-36, 41, and 46 are indefinite over the recitation of the phrase "the sequences of claim 28" in claim 33. It is unclear as to whether this language is intended to encompass the sequence of the "fragment of a nucleic acid" of claim 28, or whether this language is intended to limit the claims to particular sequences recited in the claim. Clarification is required.

Claims 33, 35-36, 41, and 46 are indefinite over the recitation of the limitations "its corresponding RNA sequences" and "its corresponding gene" in

claim 33. It is unclear as to what "its" in claim 33 refers to. Further, it is unclear as to what type of relationship between two nucleic acids is intended to be encompassed by the language "corresponding".

Claims 37-40 and 55 are indefinite over the recitation of the phrase "sequence of the region of sequence SEQ ID No. 2 comprising the GAG codon in positions 40 to 42 or its complementary strand" in claims 37 and 55. First, it is unclear as to what molecules would be encompassed by the language "sequence of" a region (e.g., would this require a molecule comprising the region, subsequences of the region, etc.). Second, there is insufficient antecedent basis for the limitation "the region of sequence...." in the claims, and further there is no clear and limiting definition in the specification as to what might constitute the "region of sequence SEQ ID No. 2 comprising the GAG codon....". Thus, it is unclear as to what "region" or portion of SEQ ID NO: 2 might be encompassed by this language. Further, it is unclear as to what "its" in claims 37 and 55 refers back to.

Claims 38-39 are indefinite over the recitation of the phrase "a sequence composed of 9 base paris [sic] upstream and 9 base paris [sic] downstream of the GAG codon in positions 40 to 42" in claims 38 and 39. It is unclear as to whether the claim is intended to be limited to a sequence of contiguous nucleotides found in SEQ ID NO: 2, or whether the claims may encompass any arrangement "9 base pairs upstream", "9 base pairs downstream", etc. Clarification is required.



Claims 42-44 are indefinite over the recitation of the limitation “primer pair...comprising the nucleotide sequence of sequences...” in claim 42. It is unclear as to whether each primer of the pair is to contain “the nucleotide sequence,” whether “the nucleotide sequence” is to be split between two primers, etc.

Regarding claim 43, it is unclear whether each primer of the pair of claim 42 must comprise 19 nucleotides, or whether this limitation applies only to one primer of the pair.

Claims 42-44 and 54-55 are indefinite over the recitation of the limitations “the nucleotide sequence of sequences adjacent to the senX3-regX3 region in the 3' of seX3 and 5' of regX3 regions” in claims 42, 54, and 55. There is insufficient antecedent basis for the limitations “the nucleotide sequence...”, “the senX3-regX3 region...”, and “the 3' of seX3 and 5' of regX3 regions” in the claims, as the claims do not previously refer to these sequences/regions. The claims should be amended so as to provide a clear and limiting structural and/or functional description of those primers that are intended to be encompassed by the claims.

Claim 44 is indefinite over the recitation of the phrase “A nucleotide primer of claim 42 comprising the pair of primers...”. It is unclear as to whether applicants' intent is for the claim to encompass a primer pair, or alternatively, a single primer comprising both of the sequences recited therein. Clarification is required.

Claim 45 is indefinite over the recitation of the phrase "the improvement comprising using as the diagnostic probe or primer a fragment of claim 28". First, there is insufficient antecedent basis for the limitation "the diagnostic probe or primer". Second, the recitation "using..." does not apprise one of skill in the art as to how said probe or primer would be used, so as to apprise one of skill in the art as to what actual steps are required of the claimed method.

Claim 46 is indefinite over the recitation of the phrase "the improvement comprising as the in vitro tool, a nucleotide probe or nucleotide primer of claim 33". First, there is insufficient antecedent basis for the limitation "the in vitro tool". Second, this recitation does not apprise one of skill in the art as to how said "in vitro tool" would be used in the claimed method, so as to apprise one of skill in the art as to what actually steps are required to accomplish "detection or diagnosis...".

Claim 55 is indefinite over the recitation of the limitations "the biological sample" and "the specific nucleic acids" in step (1), because there is insufficient antecedent basis for these limitations in the claims.

### ***Conclusion***

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Diana B. Johannsen whose telephone number is 571/272-0744. The examiner can normally be reached on Monday-Friday, 7:30 am-4:00 pm.

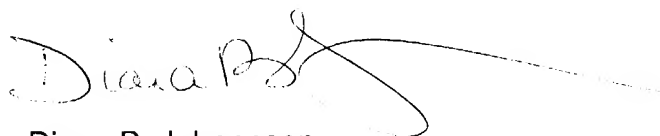
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones can be reached at 571/272-0745. The fax

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phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A handwritten signature in black ink, appearing to read "Diana B. Johannsen", with a long, sweeping horizontal line extending to the right.

Diana B. Johannsen  
Primary Examiner  
June 28, 2004